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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/489,711	01/24/2000	David S. Roberts	PC10299A	6167
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PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 12/11/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/489,711

Applicant(s)
Roberts et al.

Examiner
S. Devi, Ph.D.

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 17, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-22 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) 19-22 ~~is/are~~ withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-18 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6. 20) ☐ Other:

DETAILED ACTION

Preliminary Amendments

- 1) Acknowledgment is made of Applicant's preliminary amendments filed 08/08/01 and 10/17/01 (paper no. 7 and 9).

Election

- 2) Acknowledgment is made of Applicant's election filed 10/17/01 (paper no. 9), without traverse, of invention I, claims 12-18, drawn to a product. The corresponding method claim(s) of invention II and III will be retained as pending claims pursuant to the rejoinder provisions of M.P.E.P 821.04 and will be withdrawn from consideration until such time as the subject matter of elected product claim(s) are deemed allowable. The Examiner in charge of the instant application will then determine if corresponding method claims include all of the limitations of the allowable product claim(s) prior to determining if rejoinder will be permitted under M.P.E.P 821.04.

Status of Claims

- 3) Claims 1-5 and 8 have been canceled via the amendment filed 08/08/01.
Claims 6, 7 and 9-11 have been canceled via the amendment filed 10/17/01.
New claims 12-22 have been added via the amendment filed 10/17/01.
Claims 12-22 are pending.
Claims 12-18 have been elected via the amendment filed 10/17/01.
Claims 19-22 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.
The elected claims 12-18 are under examination.

Priority

- 4) The instant application claims domestic priority to the provisional application SN 60/117,704 filed 01/29/1999.

Information Disclosure Statement

5) Acknowledgment is made of Applicants' information disclosure statements filed 08/08/00 (paper no. 6). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 10).

Specification - Informalities

6) The instant specification is objected to for the following reason(s):

(a) The use of trademarks in the instant specification has been noted in this application. For example, see page 4, line 1; and page 7, lines 30, 31 and 32; "Span 80"; page 4, line 1; page 10, line 28; and page 7, lines 29 and 31: "Tween 80". The recitations should be capitalized wherever they appear and be accompanied by the generic terminology. Each letter of the trademark must be capitalized. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to the trademarks, wherever such recitations appear.

(b) In page 15, line 26, it is unclear what does the recitation "\$ 40.9°C" mean.

Rejection(s) under 35 U.S.C. § 102

7) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8) Claims 12, 13, 16 and 17 are rejected under 35 U.S.C § 102(b) as being anticipated by Sato *et al.* (*Vet. Microbiol.* 43(2): 173-182, 1995 - Applicants' IDS).

Sato *et al.* teach an antigenic composition comprising a culture filtrate antigen of *Erysipelothrix rhusiopathiae* culture (i.e., fluid fraction). The culture filtrate is fractionated and concentrated by ultrafiltration and mixed with aluminum phosphate gel, i.e., stabilizing agent. The antigen fraction is mixed with Freund's complete adjuvant. The composition is injected into mice. That the process of ultrafiltration concentrates the fluid fraction of the culture by about 3 to about 30-fold is inherent from the teachings of Sato *et al.*

Claims 12, 13, 16 and 17 are anticipated by Sato *et al.*

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9) Claims 12 and 14-16 are rejected under 35 U.S.C § 102(b) as being anticipated by Sawada *et al.* (*Am. J. Vet. Res.* 48: 239-242, 1987 - Applicants' IDS) as evidenced by Oaks *et al.* (US 6,277,379).

Sawada *et al.* teach an antigenic composition comprising a supernatant fluid (i.e., fluid fraction) obtained from an *Erysipelothrix rhusiopathiae* culture which is inactivated with formalin and concentrated to 10% of its initial volume (see paragraph bridging pages 239 and 240). That formalin acts as a stabilizing agent or preservative is inherent from the teachings of Sawada *et al.* in light of what is well known in the art. For instance, Oaks *et al.* teach formalin to be a common preservative used in antigen or vaccine compositions (see column 9, lines 2 and 3).

The disclosure of Sawada *et al.* anticipates the instant claims. Oaks *et al.* is **not** used as a secondary reference in combination with Sawada *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Sawada *et al.* See *In re Samour* 197 USPQ 1 (CCPA 1978).

Rejection(s) under 35 U.S.C § 103

10) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

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11) Claims 12, 17 and 18 are rejected under 35 U.S.C § 103(a) as being unpatentable over Dayalu *et al.* (WO 91/18627) in view of Sato *et al.* (*Vet. Microbiol.* 43(2): 173-182, 1995 - Applicants' IDS) and Wild RL (*J. Am. Vet. Med. Assoc.* 184: 944-949, 1984).

Dayalu *et al.* disclose a vaccine composition comprising an *Erysipelothrix rhusiopathiae* antigen extract (see page 11; and claims 18 and 19). The vaccine comprises merthiolate as a preservative, i.e., stabilizing agent (see page 17, last paragraph). The vaccine comprises a conventional adjuvant, such as, Amphigen, mineral oil and lecithin, aluminum hydroxide etc. (see page 12). Sterile mineral oil (Drakeol) containing 5-40% of lecithin, 0.7 - 32.0% Tween 80 (i.e., amphiphilic surfactant) are contained in the vaccine composition (see paragraph bridging pages 17 and 18). It is implicit that the percent concentrations of lecithin, oil and amphiphilic surfactant recited in claim 18 falls in the concentration ranges taught by Dayalu *et al.*.

Dayalu *et al.* are silent about whether or not the antigen extract is a fluid fraction from an *Erysipelothrix rhusiopathiae* culture.

The teachings of Sato *et al.* are explained above.

Wild expressly teaches that most of the immunizing antigen is found in the *Erysipelothrix rhusiopathiae* culture filtrate (see page 948, left column).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the *Erysipelothrix rhusiopathiae* antigen extract in Dayalu's vaccine composition with Sato's culture filtrate antigen of *Erysipelothrix rhusiopathiae* culture (i.e., fluid fraction) to produce the vaccine composition of the instant invention with a reasonable expectation of success. One skilled in the art would have been motivated to produce the instant invention for the expected benefit of providing, advantageously, a vaccine composition that comprises most of the immunizing antigen of *Erysipelothrix rhusiopathiae* as taught by Wild. Substituting one antigenic composition in a vaccine with another, alternative, art-known antigenic composition that comprises most of the immunizing antigen of *Erysipelothrix rhusiopathiae* would have been obvious to one skilled in the art.

Claims 12, 17 and 18 are *prima facie* obvious over the prior art of record.

Remarks

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12) Claims 12-18 stand rejected.

13) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242.

14) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.45 a.m to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 2001


S. DEVI, PH.D.
PRIMARY EXAMINER